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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/341,105	09/07/99	PONCE DE LEON	F 002076-013
		HM12/0424	EXAMINER
			SISSON, B
			ART UNIT
			PAPER NUMBER
		1655	14
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/341,105	PONCE DE LEON ET AL.
	Examiner Bradley L. Sisson	Art Unit 1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 April 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-7 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 - 5) Claim(s) _____ is/are allowed.
 - 6) Claim(s) 1-7 is/are rejected.
 - 7) Claim(s) _____ is/are objected to.
 - 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

- 18) Interview Summary (PTO-413) Paper No(s) _____.
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: _____

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 2 April 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/341,105 is acceptable and a CPA has been established. An action on the CPA follows.
2. The request for a CPA was not accompanied with any traversal of the Office action of 19 July 2000 nor was there any indication of an amendment having been filed. The absence of any traversal is taken as tacit approval of same. For convenience, the rejections as set forth in Paper No. 9, mailed 19 July 2000 are reproduced below.

Sequence Rules Compliance

3. Acknowledgement is made of applicant having filed a "REQUEST FOR PREPARATION OF A COMPUTER READABLE SEQUENCE LISTING AND STATEMENT" on 21 April 2000. Upon review of the record of Provisional Application 60/034,010, no record of a Computer Readable Form (CRF) of the Sequence Listing can be found. Accordingly, there is no CRF to transfer from the provisional application to the instant application. Applicant is therefore required to provide a new CRF and accompanying statement that the CRF and the paper copy are the same.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

6. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *In re Wands*, 8 USPQ2d 1400 (CAFC 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Quantity of Experimentation Necessary

The amount of experimentation would be profound, requiring years of testing with little if any reasonable expectation of success.

The Amount of Direction or Guidance Provided

The specification provides at best limited guidance for confirming the source of the claimed sequences and provides but an invitation for others to experiment in determining the significance of the isolated sequences. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

“ [T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue

experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F.2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').

"Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Bremer v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

"It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research.

The Presence or Absence of Working Examples

The specification shows that they have confirmed the source of the claimed nucleic acids (claims 1 and 2), and that at least some of these sequence hybridized to nucleic acid found in other avians, *i.e.* turkeys. Just what these sequences encode and what they indicate as a result of forming duplex structures with a target sequence is unknown.

It is noted with particularity that claim 5, and by default claims 1 and 3 from which claim 5 depends, is directed to the development of a genetic map for "avian species selected from the group consisting of chicken, turkey, partridge, duck, guinea hen, and goose." A review of the specification fails to find where a genetic map for such species has been developed nor where reproducible conditions have been set forth that would enable one of skill in the art to develop such a genetic map.

The Nature of the Invention

The invention relates directly to matters of physiology and chemistry, which are inherently unpredictable and as such, require greater levels of enablement. As noted in *In re Fisher* 166 USPQ 18 (CCPA, 1970):

In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

The State of the Prior Art

The area of art most to which the claimed invention is most closely related is quite undeveloped. While much effort has been spent in unraveling the nucleotide sequences of humans, and to determine which genes are encoded thereby and what conditions are associated with said sequences, little has been done with *Gallus* or other avians.

The Relative Skill of Those in the Art

The relative skill of those in the art most closely associated with the claimed invention is high, on par with those that hold a Ph.D. in biochemistry and that also have several years of laboratory experience.

While the specification does clearly identify several sequences, the specification must also enable their use. As set forth above, the specification has not been found to enable the use of the claimed sequences. While claims 3-7 are directed developing a genetic map, the specification has been found, at best, to provide only an invitation for others to experiment in the development of such. In support of this position, attention is directed to page 8 wherein is stated:

It is expected based on our results that chicken chromosome painting probes can similarly be used in closely and distantly related avian species to identify gross chromosomal rearrangements such as translocations and duplications that have occurred during avian evolution. Since the chicken Z-chromosome sequences are highly conserved in turkey, the chicken Z-chromosome-specific microsatellite markers should be particularly useful for genetic mapping in turkey. (emphasis added)

For the above reasons, and in the absence of convincing evidence to the contrary, the claims have been rejected as not being enabled by the specification.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 3-7 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: those steps needed in order to successfully map any genetically map any organism using the nucleic acid of claim 1.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 1-7 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claims 1 and 2 are drawn to a Z-chromosomal marker that need not be isolated. The specification suggests that these markers can be used in genetic mapping experiments and in fact claims methods for establishing genetic maps for a variety of avian species. The claimed nucleic acids have not been defined in terms of their encoding any specific amino acid that has been shown to have any utility. Accordingly, the only utility ascribed to these sequences is their alleged utility in developing genetic maps of a variety of avian species. The specification has not shown that such a genetic map does in fact have a substantial utility. In short, it is not clear what information these maps, which do not appear to have been in applicant's possession at the time the subject application was filed, would actually have.

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11. Claims 1-7 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

12. This is a CPA of applicant's earlier Application No. 09/341,105. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in

this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-0294 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

B.L. Sisson
Bradley L. Sisson
Primary Examiner
Art Unit 1655

BLS
April 21, 2001